Product Qualification (previously P01AD502)

1. Purpose

To establish a set of procedures, practices and expectations pertaining to the quality of items purchased by Colibrium Additive with regards to qualification of said products.

2. Scope

2.1 This document provides the General Qualification Requirements for all Colibrium Additive purchased products.

2.2 The Purchase Order will identify when these requirements shall be met.

3. Language

- "Shall" is used whenever a requirement expresses a provision that is mandatory.
- "Will" is used to describe a task that is performed by an individual or organization not governed by the document. "Will" is not to be used to express a mandatory provision. Use the term "shall".
- "Should" and "may" are used when it is necessary to express non-mandatory provisions. When a non-mandatory provision is recommended "should" is used, otherwise "may" is used.
- "Is" and "are" are used for descriptive text. No mandatory or non-mandatory requirements are expressed using these terms.
- Throughout this specification the term "Purchaser" is intended to mean Colibrium Additive and/or businesses acquired by Colibrium Additive. The term "Supplier" is intended to mean suppliers and/or planned suppliers that will provide raw materials, parts and/or assemblies to Colibrium Additive for consumption, performance of services, or for supply of Colibrium Additive customers applicable documents.

4. Product Qualification

4.1 General Guidelines

It is the responsibility of the Supplier to define and implement a detailed quality system that ensures all products supplied to Colibrium Additive are of the highest quality possible by conforming to GE or Colibrium Additive drawings and/or applicable specifications and meeting all the requirements set forth in this document.

4.2 Communication

The Colibrium Additive Purchase Order designates the Sourcing Representative who is the primary contact with the Supplier for commercial and fulfilment issues. The Supplier Quality Engineer (SQE) is the primary quality and technical contact.

4.3 Supplier Assessment

Supplier will be accessed per the supplier selection and onboarding process.

Prior to receiving a direct product purchase order, the Supplier should be assessed. Assessment criteria could include, but is not limited to, the following:

- Completion and passing of required technical capability assessment.
- EHS compliance/employment/security practices.
- Quality Management System review.

4.4 Product Qualification

After Supplier Assessment is approved, Colibrium Additive may require the Supplier to become qualified for each specific process, part or commodity family. If Colibrium Additive requires the Supplier to perform a qualification, the SQE will provide the Supplier with the Product Submission Requirements Warrant. Through the qualification process, the Supplier demonstrates ability to provide high quality products on a repeatable basis in accordance with requirements and expectations of the Colibrium Additive business purchasing the material. The qualification process applies to one product at one site and may pertain to certain pieces of equipment.

Based on Colibrium Additive business and/or site risk assessment and prioritization, all Build-to-Spec, Build-to-Print and Commercial off the shelf product suppliers may be required to complete the qualification process as described in this specification – Section 7.1.

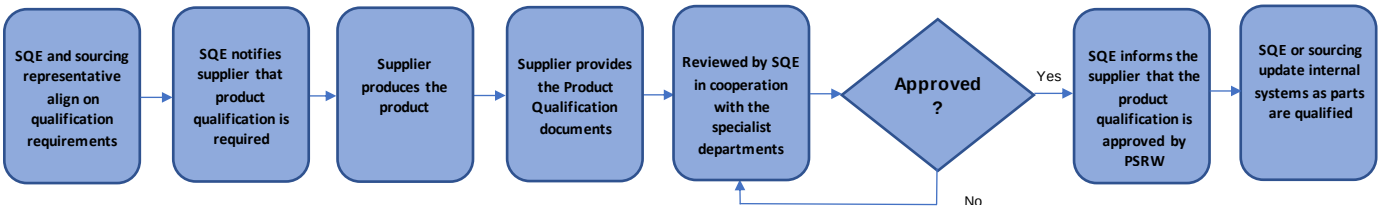

Figure 1 - Qualification Process Flow Chart

5. Roles and Responsibilities

Role	Responsibility
Supplier	Responsible for producing and providing the product and required documentation including Sub-tier supplier generated characteristics.
Supplier Quality Engineer (SQE)	Colibrium Additive representative who communicates the qualification requirements and is the key interface with the Supplier relative to qualifications, process improvements, nonconforming material dispositions, corrective actions, and surveillance auditing. SQE owns communication with the Supplier for all technical matters.
Design Engineer (DE)	Responsible for product definition. Approves change requests and has disposition authority over safety and technical product deviations.
Purchaser	Colibrium Additive and/or businesses acquired by Colibrium Additive responsible for issuing the purchase order/contract for which product or services will be supplied.
Customer	End-user of product.

5.1 Applicability and Use

Suppliers that are required to complete qualification will be formally notified by the Product Submission Requirements Warrant and will only be required for drawings / specifications known by and agreed to by suppliers.

6. General Requirements

This section details the requirements that all Suppliers shall meet.

6.1 Quality System

The Supplier should maintain a documented quality system to ensure control and conformance to the requirements of Colibrium Additive's drawings and specifications. The quality management system should meet the requirements of the current ISO 9001 (Quality management systems – Requirements) standard or equivalent. Compliance to this requirement can be demonstrated to Colibrium Additive by either of the following:

- Copy of current certification(s).
- Successful completion of a quality management systems audit by Colibrium Additive.

Any applicable industry standards (such as CE, UL, etc.) shall also be incorporated into the system. This system shall be made available to Colibrium Additive for review upon request.

6.2 Record Retention

The Supplier shall have a written procedure for the documentation and retention of quality and product records for products supplied to Colibrium Additive. The record retention period shall be a minimum of ten (10) years, from when the product was last shipped to Colibrium Additive, unless otherwise specified by Colibrium Additive or if a longer period is required by any applicable law or regulation. Records shall include, but are not limited to, product quality or inspection and test plans and results, material specifications, qualification documentation and certificates of conformance. Specific component record requirements may be specified in Colibrium Additive purchase orders, contracts or specification. It is the responsibility of the Supplier to determine the appropriate storage means to meet the retention requirement and allow for timely retrieval of records.

6.3 Specification Management at Suppliers

If the Supplier does not have the latest revision of any relevant industry specification as described in the GE or Colibrium Additive specification or drawing, it is the Supplier's responsibility to acquire the latest revision of the specification and ensure that the correct revision is being followed.

6.4 Source Inspection and Test Witness

Colibrium Additive and/or its customer may elect to inspect products, and/or witness subassemblies at the Supplier's facility during processing, testing, or at final inspection. All source inspection and test witness requirements will be identified and coordinated through the Colibrium Additive SQE, Quality Assurance, Quality representative or other designated representative. If requested, the Supplier shall provide all test samples.

6.4.1 Timing

The Supplier shall notify Colibrium Additive in advance when materials or products will be ready for inspection. The timing of this advance notification shall be a minimum of 2 weeks. Colibrium Additive may decide to visit the Supplier facility.

6.4.2 Additional Requirements

Additional requirements for Colibrium Additive and/or customer acceptance of product do not relieve the Supplier of its obligations to supply components that meet drawing and Purchase Order requirements.

6.5 Deviations

When a deviation to a requirement including a drawing, specification, packaging, or a material shortage is known or expected to exist, the Supplier shall submit a Supplier Deviation Request as early in the process as possible to the SQE and Sourcing representative. If a deviation exists or could potentially exist, an SDR shall be submitted and approved prior to shipping the deviated products. For supplier generated deviations the approved SDR applies to only the Quantities listed on the SDR. SDRs shall be submitted by the Supplier for approval of alternate materials, and other deviations to the PO requirements. SDRs shall be submitted by the primary Supplier (the Seller on the Purchase Order). Any deviations (e.g. material substitutions, etc.) related to a sub-tier supplier's scope that affect fit, form and/or function of the Supplier's product shall be submitted through the primary Supplier.

The SDR shall contain detailed description, containment, probable source and proposed remedial action (when business directed) information as part of the initial submittal. Failure to supply all of the information as required may result in the SDR being returned to the Supplier for completion of the required information. If this rejection impacts fulfillment requirements, charges may apply to the Supplier.

The Supplier shall not ship any deviating product before the SDR is approved by Colibrium Additive. The Supplier shall send a copy of the approved SDR along with the product(s) at the time of shipment. Colibrium Additive has the right to request additional inspections and tests beyond applied drawing and specifications to prove the deviated product's form, fit and function prior to SDR disposition.

No repair / rework shall be performed on a deviating/non-conforming product prior to disposition by Colibrium Additive.

Where appropriate, the Supplier shall provide a complete deviation description to include:

- Drawing/item number with zone of referenced area
- Inspection results
- Samples or photographs where applicable
- Number of defects for the lot(s) of material
- Specific Purchase Order numbers by product grouping
- Serial numbers of the components
- Estimated time to make correction(s)
- Cost related issues

For serialized parts, the serial number(s) shall be identified. For non-serialized parts, the specific Purchase Order(s) and date range shall be identified on the SDR.

For metal powder suppliers only: If a retest of any sample is determined to be deviating/nonconforming, the powder shall be rejected. In this case, the Supplier should not submit an SDR. Colibrium Additive will not approve.

6.5.1 Containment

Containment is expected to be immediate when a nonconformance is discovered, with all products affected being contained. Containment actions apply to products, process and materials in which the nonconformance was detected as well as similar products or product families in which the nonconformance may occur. If the nonconformance is discovered during random audit, all WIP, inventory and shipped but not yet received products shall be evaluated.

Containment at the Supplier is expected to isolate (separate from normal production), insulate (inspect products to sort for defects at the Supplier, in transit for shipment and at the customer site) and aid in control of risk related to the nonconformance. An effective containment process documents the Supplier's efforts to verify control of its processes, (pre-production, production and post-production). The Supplier shall document and share all containment actions.

6.5.2 Probable Source

The Supplier shall report the source of the problem considering the following, as applicable:

- Situations involving the same or similar materials, products, equipment, instruments or system abnormalities and inconsistencies in the process that are also supplied to Colibrium Additive
- Environmental conditions (e.g., temperature, humidity, light)
- Trends associated with equipment performance or specifications

6.5.3 Proposed Remedial Action

Where applicable, Suppliers to Colibrium Additive shall provide a rework or repair concept plan for all deviating products and services. Where rework or repair is not possible, substantiation shall be provided.

Rework or Repair Concept Plans shall include, as applicable:

- Identified risks that would adversely impact the product
- Planned completion date
- Estimated time (labor) required to complete correction

The Supplier shall have a positive identification plan, which ensures deviations and or corrected and or conforming materials are appropriately identified.

The Supplier shall document and show evidence to Colibrium Additive that the remedial actions have been executed. Colibrium Additive will evaluate whether the remediation execution eliminated the deviating condition or met the disposition requirements.

6.5.4 Corrective Action Procedures

When requested by the Colibrium Additive SQE, the Supplier shall perform a formal root cause analysis (RCA) and identify containment, corrective, and preventive actions using the standard RCA method & forms (8D or equivalent process). The Supplier shall provide updates on RCA to Colibrium Additive until closure. Failure to complete corrective action may result in disqualification of the Supplier.

Corrective action is intended to:

- Prevent the recurrence of the problem
- Avoid creation of further product or process issues

The Supplier shall provide and maintain objective evidence that the actions have been accomplished.

6.6 On-going Process Capability Checks

When requested, the Supplier may be required to, measure and record and analyze process data for critical to quality (CTQs) and critical to process (CTPs) or other characteristics on the drawings, specifications, or identified by the supplier. When requested, the Supplier shall provide process capability reports to Colibrium Additive. Under the direction of the SQE, the Supplier may be requested to execute improvement projects based on the process capability analysis.

7. Qualification Requirements

7.1 Product Qualification Requirements

The Supplier may be required to provide Colibrium Additive with qualification documents that include each of the Product Submission Requirements that are applicable to the Supplier's product.

Submission Requirements determined by SQE and Design Engineer will be identified on PSRW:

Requirement

1 Design Records
2 Process Flow Diagrams
3 Process Risk Assessment
4 Control Plan / Router
5 Measurement System Analysis
6 Drawing / Specification Conformity
7 Records of Material / Performance Test Results
8 Process Capability
9 Qualified Laboratory Documentation
10 Colibrium Additive Specific Requirements
11 Preservation and Packaging
12 Product Submission Requirements Warrant

When items are deemed proprietary, they can be reviewed securely with the SQE.

7.1.1 Sub-tier Suppliers

If a Supplier that is undergoing the qualification process (or is already qualified) chooses to outsource a critical process or purchase a critical component from another supplier, the Supplier shall perform a qualification and surveillance of all sub-tier suppliers in accordance with the Colibrium Additive requirements listed in this specification or equivalent. Colibrium Additive reserves the right to:

1) Review the Supplier's process for selection, qualification, and surveillance of sub-tier suppliers.
2) Approve, or disapprove, sub-tier supplier qualifications.
3) Audit and monitor the sub-tier supplier's processes and facilities when deemed necessary.

This requirement also applies if the Supplier is a sales representative or distributor that procures products that are supplied to Colibrium Additive.

7.2 Product Submission Requirements Warrant

Upon successful completion of the qualification program and receipt of the approved Product Submission Requirements Warrant or equivalent, the Supplier is released to fulfill subsequent Purchase Orders received from Colibrium Additive. This document indicates that, at the time of qualification and based on data provided by the Supplier, the manufacturing process used to produce the component(s) or perform a process was capable of complying with Colibrium Additive drawing and specification requirements. Qualification approval does not relieve the Supplier of the full responsibility, on subsequent orders, to assure the manufacturing processes remain in control and the product or process supplied meets all drawing and specification requirements, unless formal, written approval for a deviation is obtained from Colibrium Additive via a Supplier Deviation / Engineering Change Request (SDR).

Any changes to the approved manufacturing process shall be formally communicated to the SQE by the supplier and approved by Colibrium Additive before changes are implemented. Requalification of the product may be required.

8. Ongoing Quality Requirements

8.1 Documentation

After receiving the approved Product Submission Warrant or equivalent, the Supplier may be requested to provide documentation with each shipment.

Examples include:

- Certificate of Conformance
- Dimensional Results
- Coating Certificates
- Welding Reports
- Part Mark Verification
- Approved Supplier Deviation Reports

9. References and related documents

The following documents form a part of this specification to the extent specified herein. Unless otherwise indicated, the latest revision shall apply.

	Internal References	Description
01	PSRW	Colibrium Additive Product Submission Requirements Warrant
02	Product Qualification Requirements	Colibrium Additive Product Qualification Requirements Definition
03	SDR	Supplier Deviation / Engineering Change Request
04	Supplier First Article Inspection Report Requirements	Colibrium Additive FAI Work Instruction
	External References	**Description**
01	ISO 9001	Quality Management System Requirements
02	ISO 12100	Safety of machinery – General principles for design – Risk assessment and risk reduction

10. Definitions and Acronyms

Colibrium Additive definitions and acronyms This is the link to the overall Colibrium Additive definitions and acronyms. Particular ones, can be found below.

- Build-to-Print Part – A part that is manufactured according to a GE or Colibrium Additive drawing and associated GE or Colibrium Additive specifications called out on that drawing.
- Build-to-Specification (Non-Build-to-Print) Part – A part that is manufactured to meet the requirements of a GE or Colibrium Additive functional specification rather than a GE or Colibrium Additive drawing.
- Certificate of Conformance (CoC) – an official document that serves as verification that a product or service adheres to specific standards and regulations.
- Characteristic – The dimensional, visual, functional, mechanical, and material features or properties that describe and constitute the design of an item, and can be measured, observed, or identified to determine conformance to the design requirements.
- Containment – Actions taken to minimize or eliminate the risk to Colibrium Additive, or its customers associated with a nonconformance for product already produced or in process of being produced.
- Corrective Action – Actions taken remove the causes of an existing nonconformity or undesirable situation on the next product produced.
- Critical for Safety (CTS) – Those Characteristics of a process critical to safety.
- Critical to Process Characteristic (CTP) – Those Characteristics of a process that combine to define a Critical to Quality Characteristic; or are deemed essential for quality assurance purposes.
- Critical to Quality Characteristic (CTQ) – Those Characteristics of an item which if nonconforming, may prevent or seriously affect the unit performance, reliability, producibility, or customer satisfaction of a product.
- Engineering Change Request (ECR) A document submitted by the Supplier (May be Colibrium Additive Supplier Deviation / Engineering Change Request form (SDR)) to request engineering approval prior to implementing a change in design for the Supplier or its sub-tier supplier.
- Failure Mode and Effect Analysis (FMEA) - A systematic, proactive method for evaluating a process or system to identify where and how it might fail and to assess the relative impact of different failures.
- Manufacturing Process Plan (MPP) – A detailed, step-by-step sequence of operations and requirements by which products are manufactured.
- Nonconformance – A product that does not comply with the Purchaser or Supplier specification/drawing or was produced outside of approved process, work instructions or procedures.
- Non-Destructive Testing (NDT) – Analysis techniques used to evaluate properties of material, component or system without causing damage. Typical methods would include ultrasonic, magnetic-particle, liquid penetrant, radiography, eddy-current testing, etc.
- Off-the-Shelf Products – Products are packaged solutions listed in a catalog which are then adapted to satisfy the needs of the purchasing organization.
- Preventive Action – Action taken to eliminate the cause(s) of a potential nonconformance or undesirable potential situation to prevent occurrence of same or similar situations in the future.
- Product Quality Plan (PQP) – A detailed, step-by-step list of operations and requirements in which a supplier identifies a process of how, what, why, when and who will perform tests or inspections and the applicable acceptance criteria. This may also be referred to as an Inspection and Test Plan (I.T.P.).
- Product Safety Risk Assessment – Safety risk assessment for any supplier designed product in accordance with the principles defined by ISO 12100. Residual risk information should be provided to the Colibrium Additive Qualification Team.
- Qualification Package – All required documentation for a qualification. This may also be referred as Qualification Book /Documents.
- Repair – A type of correction performed to a nonconformance that reduces but does not completely eliminate the nonconformance(s) such that the product is determined to be usable for its intended purpose.
- Request for Design Change – A document submitted by the Supplier to request Colibrium Additive Engineering's approval prior to implementing a change in design for the Supplier or its sub-tier supplier.

- Rework – A type of correction performed to a nonconformance that completely eliminates the nonconformance(s) such that the product is determined to be conforming to specification or requirement in all respects.
- Scrap – A disposition for nonconforming product that renders the material not useable for its intended purpose and/or that cannot be economically reworked or repaired in an acceptable manner.
- Sourcing Representative – Colibrium Additive representative who is authorized to negotiate price, delivery, terms and conditions, and place the Purchase Order for qualification and production. The Sourcing Representative owns communication with the Supplier for all commercial and fulfilment matters.
- Sub-tier Supplier A secondary source, other than Colibrium Additive, and selected by the contracted supplier to provide a process, component, or material for incorporation into Colibrium Additive product.
- Supplier Deviation Request (SDR) – A request initiated by the Supplier to deviate from purchase order technical requirements (drawings, specifications, engineering instructions, etc.) or the approved qualification package.
- Supplier Quality Engineer (SQE) – Colibrium Additive representative who communicates the qualification requirements and is the key interface with the Supplier relative to qualifications, process improvements, nonconforming material dispositions, corrective actions, and surveillance auditing. SQE owns communication with the Supplier for all technical matters. Build-to-Print Part – A part that is manufactured according to a GE or Colibrium Additive drawing and associated GE or Colibrium Additive specifications called out on that drawing.

11. Change Log

Date of change	Change(s)	Approved By
2025-01-14	Re-format entire document for release in OMS, including revised branding (GE Additive changed to Colibrium Additive). **Section 7.1** Removal of Levels for Submission Requirements **Section 7.2** SDR name changed to Supplier Deviation / Engineering Change Request	T. Shank
2022-06-01	Rewritten to improve the qualification process and define requirements.	M. King
2020-07-07	Updated to clarify requirements for the SQEs and suppliers (Ref. AdEng-100253.A).	A. Sprague
2020-02-12	Original	A. Sprague